

REMARKS

Applicants have carefully reviewed the Office Action mailed on February 16, 2011, in which claims 28, 30-32, 36, 37, 50, 54, 56-57, 63, and 85-95 are pending and have been rejected and claims 43, 53, 55, 58-59, 62, 65-66, and 78-79 have been withdrawn from consideration. Claims 28 and 50 have been amended and claims 88, 89, 91, and 92 have been canceled. Support for the amendment is found in the specification, claims, and drawings as originally filed. No new matter has been added. Favorable further examination is requested in light of the following remarks.

Claim Rejections - 35 U.S.C. §103

Claims 28, 30-32, 36, 37, 50, 54, 56-57, 63, and 85-95 were rejected under 35 U.S.C. §103(a) as being unpatentable over Maseda (U.S. Patent No. 6,514,237) in view of Couvillon (U.S. Patent Publication No. 2003/0236531). After careful review, Applicants respectfully traverse the rejection, however in the interest of advancing prosecution, claim 28 has been amended to recite:

28. (Currently Amended) A medical device comprising
an elongate body adapted for insertion into a body lumen, said elongate body having distal and proximal ends and an axis;
an inflatable balloon disposed about a distal region of the elongate body; and
an active region comprising a conductive polymer disposed over the elongate body and at least partially beneath the inflatable balloon, wherein said active region is configured to volumetrically expand in when exposed to an electrical potential;
a passive deformable member disposed over the elongate body and beneath the inflatable balloon;
a first marker slidably disposed about the elongate body and engaged to the active region; and
a second marker fixedly disposed about the elongate body, and wherein the passive deformable member is disposed between the proximal marker and the distal marker, wherein, when said active region is exposed to said electrical potential, said active region slides the first marker along the elongate body towards the second marker, causing said passive deformable member to expand in at least one radial dimension, thereby moving at least a portion of the inflatable balloon from a substantially uninflated state to a first expanded state.

None of Masceda, Couvillon, or a combination thereof appears to teach or suggest the claimed structure. Elements from dependent claims 91 and 92 have been included in claim 28. Regarding claims 91-92, the Office Action appears to rely on Couvillon, asserting:

Regarding claim 91, a first marker (proximal 112; Figure 10B) is slidably disposed about the elongate body and engaged to the active region; and a second marker (distal 112; Figure 10B) fixedly disposed about the elongate body, and wherein the passive deformable member is disposed between the proximal marker and the distal marker (Figure 7A and 7B).

See page 6, lines 2-7. Applicants respectfully disagree. Couvillon does not appear to provide any indication that elements 112 include a slidable element and a fixed element, as asserted by the Office Action. Further, Couvillon specifically defines element 112 as “active member 112 of FIG. 10A comprises an electroactive polymer.” See paragraph 73. Applicants submit that element 112 of Couvillon cannot be considered to be markers based on the specific teaching of the reference that this element is an active element. Couvillon do not appear to teach markers in the embodiment shown in FIG. 10. If the Office Action is considering one or both of the electrodes 114, 118 as the claimed markers, there is no teaching or suggestion that one of these electrodes is slidably disposed about an elongate body and engaged to the active region while the other electrode is fixedly disposed about the elongate body.

Additionally, in this portion of the rejection, the Office Action has not indicated which element in Couvillon is considered the “active region” however, on page 5, line 18, the Office Action asserts Couvillon teaches a sealed structure 120 “encloses the active region, an electrolyte 114 and a counter electrode 118” which appears to be in reference to FIG. 10A-10C. It thus appears the Office Action is considering element 112 as the active region, as this is the only other structure enclosed by element 120. The Office Action’s apparent reliance on element 112 as both the active region and a marker is not understood. Regardless of which elements in FIG. 10 of Couvillon are considered markers, none of the elements are described by Couvillon as being slidably disposed about an elongate body, as recited in the claims.

Further, disposing an active region at least partially under an inflatable balloon is not obvious over Masceda. Masceda teaches, as noted by the Examiner, that the activation of the

EAP strands may induce move such as expansion. Column 3, lines 50-54. Maseda teaches an embodiment in Fig. 5A and column 6, lines 45-51 that uses EAP strips to induce a radial expansion of a second of the catheter. Significantly, Maseda teaches that such an embodiment can “expand like a balloon” but does not teach such strips actually expanding an inflatable balloon. Column 6, line 51. Maseda goes on to teach “for example, the balloon 118, which is also flexible, may incorporate the composite strands.” Column 8, lines 8-9. However, Maseda does not teach that such strands expand radially or are used to inflate the balloon. Strands incorporated into the balloon may be used, for example, to change the stiffness or shape of the balloon rather than to inflate it. Moreover, Maseda teaches that a composite strand 306 may be attached to the outer tubular body substantially along its entire length and can be used to alter the stiffness of the tubular body. Column 5, line 56 – column 6, line 3. However, Maseda does not teach or illustrate that the strand of the embodiment causes the tubular body to become radially enlarged when activated. Thus even if Maseda teaches that it might be obvious to put an active region at least partially under the balloon, Maseda still fails to teach or suggest doing so in such a manner so as to cause radial expansion of the balloon.

Also, the combination of Maseda and Couvillon is non-obvious. The Office Action suggests that using the actuators of Couvillon in Maseda would be obvious because of the balloon-like profile of the malecot element 104 of Couvillon. However, malecots and balloons are expanded in quite different ways. Balloons are expanded through providing pressure in their cavities, while malecots are expanded by bringing their ends closer together. Balloons of the sort used in stent delivery are typically folded around the inner elongate member when collapsed. Bringing the ends of a balloon together will simply create a differently folded balloon and not create any radial expansion. Moreover, Couvillon fails to teach any radial expansion of the actuating members, either in the Figures or in the text of the specification. Figure 7A shows actuators 110a longitudinally contracted and 110b longitudinally expanded and Figure 7B shows actuators 110a longitudinally expanded and 11b longitudinally contracted (and malecot element 104 expanded). In Figure 7A and likewise in Figure 7B, actuators 110a and 110b are the same width. If there was any radial expansion of the actuators, these figures would show some difference in relative width of the

actuators. No radial expansion is taught with respect to the embodiments of Figures 10a, b and c either. Thus, one would not use the actuators of Couvillon in Maseda for at least two reasons. First, longitudinally expanding and contracting actuators would not radially expand a balloon. And second, the actuators of Couvillon do not radially expand.

For at least these reasons, therefore, Applicants submit that claim 28 is patentable over the cited art.

Additionally and with particular regard to independent claim 50: Maseda discloses a conventional balloon catheter expanded via an inflation lumen and also discloses, as discussed above, an EAP strip configuration that can expand like a balloon. Maseda fails to suggest combining the two into a balloon that can be partially expanded using electrically actuated members and then further expanded using inflation media as claimed. Maseda might suggest the substitution of EAP elements for a balloon but fails to teach or suggest supplementing the conventional inflation media means for expanding a balloon with EAP elements.

Further, neither Maseda nor Couvillon appear to teach or suggest a balloon catheter in which one or more electrically actuated members are bands disposed around the catheter shaft, in a recess, where the electrically actuated member is flanked with proximal and distal markers, as recited in claim 50.

For these reasons as well as for those reasons discussed above with respect to claim 28 pertaining to Maseda and Couvillon, Applicants submit that that claim 50 is likewise patentable over the cited art.

As claims 30-32, 36, 37, 54, 56-57, 63, and 85-95 depend from one of claims 28 and 50 and contain additional elements, Applicants submit that these claims are allowable for at least this reason.

Further, with regard to claims 87-93: several additional objections to the rejections arise.

With regard to claims 87-90: These claims are rejected off a combination of Maseda and Figs. 10a and 10c of Couvillon. These figures are diagrammatic views of actuating members according to Couvillon and in both of them, there is an intervening layer 120. Thus, if one makes the proposed modification, the limitation of claim 50, from which claims 87-90

depend of “such that the outer surface of the one or more electrically actuated members contacts the inner surface of the inflatable balloon” is not met.

Further, with regard to claims 87-93: paragraph 74 is cited for teaching that electrodes 118 can be considered radiopaque bands. This paragraph supports the assertion that the electrodes may be radiopaque, but does not support that they are in the form of a band. A band is a piece of material in the form of a hollow cylinder open on both ends. The electrodes are not such. In Figs. 7A and 7B, for example, actuators 110a and actuators 110b are taught. Thus no single actuator encircles the tubular member.

Further, claim 87 recites “wherein a first active region is disposed over a first conductive radio-opaque band and wherein a second active region is disposed over a second conductive radio-opaque band that is positioned distal to said first conductive radio-opaque band.” Fig. 10 discloses a single conductive radiopaque band 118 disposed over a first active region 112, but none of the embodiments disclose the reverse: an active region disposed over a radiopaque band.

Further, claim 90 recites “wherein the proximal marker and the distal marker are configured to have an outer diameter that is greater than the outer diameter of the one or more electrically actuated members when the one or more electrically actuated members are in a non-activated state.” Fig. 10C is the only figure in which more than one electrode 118 is taught (and thus arguably meeting the language of proximal and distal markers), and this figure clearly shows that the one or more electrodes 118 are not configured to have an outer diameter greater than that of the one or more electrically actuated members when in a non-activated state. They have the same thickness. Further, none of these actuators are in the form of a circle or cylinder and thus do not even have diametral dimensions.

For these additional reasons, as well as those discussed above with respect to claims 28 and 50, Applicants submit that these claims are in condition for allowance.


Conclusion

Reconsideration and further examination of the rejections are respectfully requested. It is respectfully submitted that all pending claims are now in condition for allowance. Issuance of a Notice of Allowance in due course is requested. If a telephone conference might be of assistance, please contact the undersigned attorney at (612) 677-9050.

Respectfully submitted,
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By their Attorney,

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